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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,167	06/05/2002	Ron Naaman	NAAMAN=2	8340

1444 7590 07/25/2005

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EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,167	NAAMAN ET AL.	
	Examiner	Art Unit	
	Christopher M. Babic	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/27/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's arguments and subsequent amendments, see response to restriction requirement: amendment and remarks, filed dated March 29, 2005, with respect to the lack of unity requirement under rules 13.1 and 13.2 of PCT rules, have been fully considered and are deemed persuasive. The lack of unity requirement between Groups I (Claims 1 and 5-17) and Group II (Claims 17-19) is hereby **withdrawn**. All claims will be examined on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure

sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the use of the legal phraseology "said". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is confusing because of the language "characterized in that", as the scope is unclear. It is suggested that conventional U.S. claim language such as "comprising" be used in amended claims. Claims 2-16 are rejected due to their dependence on a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1 and 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahen et al. (WO 98/19151), in view of Hashimoto et al. (U.S. 5,972,692).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

These claims are drawn to a semiconductor device composed of one or more insulating or semi-insulating layers, one conducting semiconductor layer,

two conducting pads, and a layer of at least one single-stranded DNA probe, characterized in that: said conducting semiconductor layer is on top of one of said insulating or semi-insulating layers, said two conducting pads are on both sides on top of an upper layer which is either said conducting semiconductor layer or another of said insulating or semi-insulating layers, making electrical contact with said conducting semiconductor layer, and said layer of at least one single-stranded DNA probe is directly adsorbed on the surface of said upper layer, between the two conducting pads, wherein exposure of said single-stranded DNA probe to a sample containing a target DNA or RNA, under hybridization conditions, causes either a current change resulting from the hybridization process when a constant electric potential is applied between the two conducting pads or a change in the electric potential required to keep a constant current.

Regarding Claim 1, Cahen et al. discloses a hybrid organic-semiconductor device characterized by being composed of: (i) at least one layer of a conducting semiconductor; (ii) at least one insulating layer; (iii) a multifunctional organic sensing molecule directly chemisorbed on one of its surfaces, said multifunctional organic sensing molecule having at least one functional group that binds to said surface and at least one other functional group that serves as a sensor; and (iv) two conducting pads on the top layer making electrical contact with the electrically conducting layer (1), such that electrical current can flow between them at a finite distance from the surface of the device (Abstract; Page 4, Lines 3-13; Figures 1, 2). In addition, Cahen et al. disclose a semiconductor

device wherein: said conducting semiconductor layer is on top of one of said insulating or semi-insulating layers, said two conducting pads are on both sides on top of an upper layer which is either said conducting semiconductor layer or another of said insulating or semi-insulating layers, making electrical contact with said conducting semiconductor layer (Fig 2A, 2B). Cahen et al. does not disclose a layer of single-stranded DNA or RNA directly adsorbed to an upper layer which is either said conducting semiconductor layer or another of said insulating or semi-insulating layers wherein exposure of said single-stranded DNA probe to a sample containing a target DNA or RNA, under hybridization conditions, causes either a current change resulting from the hybridization process when a constant electric potential is applied between the two conducting pads or a change in the electric potential required to keep a constant current.

Kashimoto et al. disclose a gene detection method wherein a single-stranded nucleic acid probe having a base sequence complementary to the gene to be detected is immobilized onto the surface of an electrode, and the nucleic acid probe is reacted with the gene sample denatured to a single stranded form, and then the nucleic acid probe is hybridized with the gene to be detected (Abstract; Column 2, Lines 25-50; Column 14, Example 1). They disclose immobilization of single-stranded nucleic acid probes to a base plate of a semiconductor element (Column 26, Lines 21-27; Column 27, Line 1). They disclose a semiconductor electrode of various materials including GaAs (Column 8, Lines 44-55). They disclose immobilization of a nucleic acid probe to an electrode through physical adsorption (Column 9, Lines 66-67; Column 19, Lines

10-11). They disclose multiple examples wherein gene detection was measured by determining the oxidation-reduction current change produced by hybridization of the test sample (Column 14, Example 1; Column 23, Example 17; Column 24, Example 18; Column 30, Example 19).

Regarding Claim 5, Cahen disclose a semiconductor device, wherein the semiconductor material is selected from a III-V and a II-VI material, or mixture thereof, wherein III, V, II, and VI denote the Periodic Table elements III=Ga, In; V=As, P; II=Cd, Zn; VI=S, Se, Te (Page 5, Lines 9-12).

Regarding Claim 6, Cahen et al. disclose a semiconductor device, wherein the semiconductor material is doped n-GaAs or n-(Al,Ga)As (Page 5, Lines 12-15).

Regarding Claim 7, Cahen et al. disclose a semiconductor device, wherein a dielectric insulating material is selected from a III-V and a II-IV material, or mixtures thereof, wherein III, V, II, and VI denote the Periodic Table elements III=Ga, In; V=As, P; II=Cd, Zn; VI=S, Se, Te (Page 7, Lines 12-16).

Regarding Claim 8, Cahen et al. disclose a semiconductor device, wherein the undoped semiconductor is undoped GaAs (Page 7, Line 16).

Regarding Claim 9, Cahen et al. disclose a semiconductor device, wherein said conducting semiconductor layer is a layer of doped n-GaAs which is on top of a semi- insulating layer of (Al,Ga)As which is on top of another semi- insulating layer of GaAs (Page 8, Lines 12-30; Page 9, Lines 1-14; Fig 2A, 2B). They disclose a thin layer of a multifunctional organic sensing molecule adsorbed on

the undoped GaAs surface (Page 9, Lines 11-12; Fig 2A,2B). Cahen does not disclose a layer of at least one single-stranded DNA probe.

Kashimoto et al. disclose immobilization of single-stranded nucleic acid probes to a base plate of a semi-conductor element (Column 26, Lines 21-27; Column 27, Line 1). They disclose immobilization of a nucleic acid probe to an electrode through physical adsorption (Column 9, Lines 66-67; Column 19, Lines 10-11).

Regarding Claim 10, Cahen et al. disclose a semiconductor device, wherein said conducting semiconductor layer is a layer of doped n-(A1,Ga)As which is on top of an insulating layer of undoped GaAs which is on top of a semi-insulating layer of GaAs, on top of said conducting semiconductor doped n-(A1,Ga)As layer there is a semi- insulating undoped (Al,Ga)As layer on top of which there is an upper undoped GaAs semi-insulating layer (Page 8, Lines 12-30; Page 9, Lines 1-14; Fig 2A, 2B). They disclose a thin layer of a multifunctional organic sensing molecule adsorbed on the undoped GaAs surface (Page 9, Lines 11-12; Fig 2A,2B). Cahen does not disclose a layer of at least one single-stranded DNA probes.

Kashimoto et al. disclose immobilization of single-stranded nucleic acid probes to a base plate of a semi-conductor element (Column 26, Lines 21-27; Column 27, Line 1). They disclose immobilization of a nucleic acid probe to an electrode through physical adsorption (Column 9, Lines 66-67; Column 19, Lines 10-11).

Regarding Claim 11, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose wherein said single-stranded DNA probes comprise a sequence complementary to a sequence of a target DNA or RNA.

Kashimoto et al. disclose nucleic acid probes that have a base sequence complementary to the entire or part of a target base sequence (Page 6, Lines 65-67; Page 7, Lines 1-7).

Regarding Claims 12 and 13, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose wherein multiple single-stranded DNA probes comprise a sequence complementary to a mutation sequence of a gene responsible for a genetic disease or disorder.

Kashimoto et al. disclose multiple nucleic acid probes that have a base sequence complementary to the entire or part of a target base sequence of a gene causing a genetic disease (Page 7, Lines 40-45). They disclose employing a base plate having a grid with at least two types of nucleic probes immobilized thereon (Column 26, Lines 55-60). They disclose examining a plurality of genes on the same base plate (Column, Lines 13-22).

Regarding Claim 14, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen et al. also disclose that the sensitivity of their semiconductor device does not depend linearly on its surface area and it is able to use the same solid state structure with different adsorbed multifunctional organic sensing molecules, subsequently making it able to be

constructed as a sensor of small semiconductor devices capable of processing a large variety of chemicals (Page 14, Lines 1-28). Cahen does not disclose each device carrying a different DNA probe.

Kashimoto et al. disclose employing a base plate having a grid with at least two types of nucleic probes immobilized thereon (Column 26, Lines 55-60). They disclose examining a plurality of genes on the same base plate (Column, Lines 13-22).

Regarding Claim 15, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose a device of the sensor array carrying a DNA probe comprising a sequence complementary to a sequence of a target DNA or RNA.

Kashimoto et al. disclose nucleic acid probes that have a base sequence complementary to the entire or part of a target base sequence (Page 6, Lines 65-67; Page 7, Lines 1-7).

Regarding Claim 16, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose a device of the sensor array carrying a DNA probe comprising a sequence complementary to a mutation sequence of a target gene responsible for a genetic disease or disorder and at least another of said devices in the array carries a control DNA probe comprising a sequence complementary to the sequence of the normal gene corresponding to said mutation.

Kashimoto et al. disclose multiple nucleic acid probes that have a base sequence complementary to the entire or part of a target base sequence of a

gene causing a genetic disease (Page 7, Lines 40-45). They disclose employing a base plate having a grid with at least two types of nucleic probes immobilized thereon (Column 26, Lines 55-60). They disclose examining a plurality of genes on the same base plate (Column, Lines 13-22).

Regarding Claim 17, the semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose a method for the detection of a target DNA or RNA which comprises: exposing the single-stranded DNA probe of at least one semiconductor device to a sample containing the target DNA or RNA, under hybridization conditions; and monitoring either the current change resulting from the hybridization process when a constant electric potential is applied between the two conducting pads or measuring the change in the electric potential required to keep a constant current.

Kashimoto et al. disclose a gene detection method wherein a single-stranded nucleic acid probe having a base sequence complementary to the gene to be detected is immobilized onto the surface of an electrode, and the nucleic probe is reacted with the gene sample denatured to a single stranded form, and then the nucleic acid probe is hybridized with the gene to be detected (Abstract; Column 2, Lines 25-50; Column 14, Example 1). They disclose immobilization of single-stranded nucleic acid probes to a base plate of a semiconductor element (Column 26, Lines 21-27; Column 27, Line 1). They disclose a semiconductor electrode of various materials including GaAs (Column 8, Lines 44-55). They disclose immobilization of a nucleic acid probe to an electrode through physical adsorption (Column 9, Lines 66-67; Column 19, Lines 10-11). They disclose

multiple examples wherein gene detection was measured by determining the oxidation-reduction current change produced by hybridization of the test sample (Column 14, Example 1; Column 23, Example 17; Column 24, Example 18; Column 30, Example 19).

Regarding Claims 18 and 19, the methods for DNA or RNA detection and semiconductor device disclosed by Cahen has been outlined in the previous paragraphs. Cahen does not disclose wherein said single-stranded DNA probes comprise a sequence complementary to a sequence of a target DNA or RNA.

Kashimoto et al. disclose nucleic acid probes that have a base sequence complementary to the entire or part of a target base sequence (Page 6, Lines 65-67; Page 7, Lines 1-7).

Furthermore, Kashimoto et al. discloses several advantages of their methods over the prior art, such as a safer and more convenient gene detection method that circumvents the use of dangerous nucleic acid probes (Abstract, Column 1, Lines 54-67; Column 2, Lines 1-23).

One of ordinary skill in the art would have been motivated to practice the methods disclosed by Kashimoto (i.e. detection of nucleic acid hybridization through the use of a semiconductive surface) with the semiconductive device disclosed by Cahen because of, among other advantages, the advantage of a safer and more convenient gene detection method that circumvents the use of dangerous (i.e. radioactive) nucleic acid probes. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

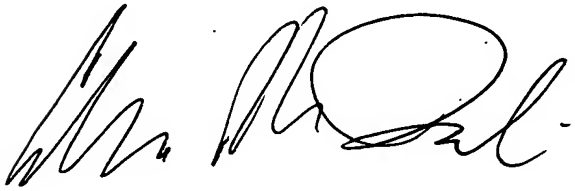
Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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7/21/05